EXHIBIT 236

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd. 3rd Floor Parsippany, NJ 07054 (973) 526-6000	10/29,31;11/1,5,6,15,29/01
	FEI NUMBER 2244683

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jasmine Shah. M.S., R Ph. Director Regulatoey Affairs

FIRM NAME	STREET ADDRESS
Amide Pharmaceutical, Inc	101 East Main Street
CITY, STATE AND ZIP CODE Little Falls, NJ 07424	TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

1. During the packaging of [redacted], thin tablets were observed by packaging personnel. A portion of the batch (drums 4,7,8 & 11) was visually inspected for the presence of thin tablets, which resulted in approximately 1,600 tablets being rejected and ultimately the rejection of drums 4, 7, 8 and 11. The entire contents of drums 1, 2, 3, 5, 6, 9 and 10 were packaged, during the packaging, the packaging line was run at a slower speed so that thin tablets could be observed on the tracks.

   a. There is no assurance that all short weight/thin tablets were rejected from the batch.
   b. There was no rework procedure written for the tablet inspection of drums.
   c. During operational/performance qualification studies and compression start-up, 10 of 32 stations of the tablet press are checked for weight and thickness. Therefore, there is no assurances that all 32 stations of the tablet press yield tablets within specifications for weight and thickness.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Nancy Rolli	Nancy Rolli, Investigator	11/29/01

FORM FDA 483 (8/00) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 1 PAGES

PLAINTIFF'S EXHIBIT 236

Amide
PHARMACEUTICAL, INC.

101 East Main Street
Little Falls, New Jersey 07424
Telephone (973) 890-1440
Fax (973) 890-7980

December 10, 2001

Douglas I. Ellsworth, Director
New Jersey District
United States Food and Drug Administration
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Dear Mr. Ellsworth,

We respectfully submit this letter and its enclosures in response to form FDA 483, Inspectional Observations, presented to Mr. Jasmine Shah, Director Regulatory Affairs of Amide Pharmaceutical, Inc. The observation was submitted by FDA Investigator Ms. Nancy Rolli on November 29, 2001.

Before addressing the observation, Amide wishes to express its appreciation to the investigator, Ms. Rolli, for her courtesy and cooperation during the inspection.

We have taken the appropriate actions to correct amendable deficiencies and have implemented procedures to preclude their recurrence wherever possible.

The Inspectional Observation and Amide's corresponding response is enclosed along with this letter.

1. During the packaging of [redacted], thin tablets were observed by packaging personnel. A portion of the batch (drum 4, 7, 8 & 11) was visually inspected for the presence of thin tablets, which resulted in approximately 1,600 tablets being rejected and ultimately the rejection of drums 4, 7, 8 & 11. The entire contents of drums 1, 2, 3, 6, 9, and 10 were packaged, during the packaging, the packaging line was run at a slower sped so that thin tablets could be observed on the tracks.

   a. There is no assurance that all short weight/thin tablets were rejected from the batch.

   b. There was no rework procedure written for the tablet inspection of drums.

   c. During operation/performance qualification studies and compression start-up, 10 of 32

stations of the tablet press are checked for weight and thickness. Therefore, there is no assurance that all 32 stations of the tablet press yield tablets within specifications for weight and thickness.

Response: When thin tablets were observed during packaging of [redacted], an investigation was initiated and an investigation report was issued.

[redacted] are round, green colored tablets. In addition to thickness measurement, potentially "thin" tablets may also be discerned by observing the tablets color. Normally green tablets appear significantly lighter in overall color. This obvious attribute allows reliable visual inspection. The entire batch was inspected as follows:

The top portion of the each drum was inspected by packaging personnel and QA. The drums in which thin tablets were observed were placed on hold. The drums in which no thin tablets were observed were permitted to proceed to product packaging, subject to additional visual inspection.

Both packaging and QA operators closely observed the tablets during the hopper feed operation.

In addition, packaging operators and QA observed the tablets as they vibrated down the tracks into the filling apparatus. The speed of the vibrator/filler was decreased sufficiently to allow the visual detection of any thin tablets.

No thin tablets were observed during the packaging of these drums.

Drums containing thin tablets underwent table, visual inspection. As a precaution, all these drums were later rejected.

In response to the aforementioned observation, the following actions have been are initiated to avoid future occurrences:

a. In order to handle this type of problem in the future, Amide has purchased tablet sorting equipment that will sort thin/thick tablets. Enclosed is a purchase order copy for the equipment (Attachment 1). Upon receipt of the equipment, an IQ/OQ/PQ will be performed and the equipment will be used if such a situation arises.

b. Since the inspection was performed online, a rework procedure was not written. In the future, any unforeseen inspection to be performed will be done using a rework procedure.

c. Amide has implemented a procedure specifying that at least one tablet from each station will be evaluated during start-up of the tablet press. Enclosed is the DOI referencing the revised procedure (Attachment 2).

We have responded to these Inspectional Observations in a prompt and positive manner, and we commit ourselves to a continuing review of all products and procedures to assure compliance with regulations.

Upon completion of your review, please contact me to discuss any outstanding issues or additional clarifications you may require.

Very Truly Yours
AMIDE PHARMACEUTICAL,

Jasmine Shah, M.S., R.Ph.
Director-Regulatory Affairs

Enc. Inspectional Observations and Response.

cc. Nancy Rolli, Regina Brown